

K123980 SONICONE PLUS ULTRASOUND WOUND CARE SYSTEM AND ACCESSORIESMar 5, 2013
69 days to decisionK123980 · Product code: **NRB** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k123980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wound Cleaner, Ultrasound (NRB)
Date received	Dec 26, 2012
Decision date	Mar 5, 2013
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Misonix, Inc.
Location	Farmingdale, NY, US
Contact	RONALD MANNA
Website	http://www.misonix.com/
510(k) history	17 submissions · 17 cleared · 1998-2022

Misonix, Inc. specializes in ultrasonic surgical and wound care devices, with a manufacturing facility in Farmingdale, US. The company developed core technologies for minimally invasive surgical applications and therapeutic ultrasound systems. Misonix received FDA 510(k) clearances from total submissions between 1998 and 2022. All cleared devices fall within the General & Plastic Surgery category. The company's regulatory record reflects sustained focus on ultrasonic surgical aspirators, lesion-generating systems, and ultrasonic wound care platforms. The company is inacti...